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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,243	02/16/2001	John D. Dobak III	008003	4416

7590 06/18/2003

Innercool Therapies
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EXAMINER

KEARNEY, ROSILAND STACIE

ART UNIT	PAPER NUMBER
3739	19

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/785,243	JOHN D. DOBAK <i>CR</i>
	Examiner Rosiland S Kearney	Art Unit 3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 April 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1 and 6-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1 and 6-11 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not adequately disclose a blood flow passageway through the partially helical shape as recited in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginsburg further in view of Saab '392 and Arless '898

Ginsburg discloses a method and apparatus for causing hypothermia. Ginsburg teaches a catheter (figure 11) with a heat transfer element (162) at its distal tip, inserting

the catheter through the vascular system and cooling blood flowing in that portion of the vascular system which also cools the organ associated with that particular vessel being cooled (col. 4 lines 5-13). Ginsburg discloses that the coolant is circulated throughout the device but is moot as to what happens to the fluid once it exits port (38). Therefore, Ginsburg teaches all of the limitations of the claims except returning the fluid to a chiller, providing a coaxial catheter, insulating the supply lumen, the heat transfer element being metallic and the heat transfer element being helical.

Saab discloses a similar device and teaches that it is old and well known in the art to provide a coaxial structure which provides a means of differential heating (col 11 lines 27-45), also to provide a chiller that recycles spent heat transfer fluid (col. 9 lines 60-65) and to insulate the supply lumen to prevent cooling of tissue not intended for treatment located in close proximity to the device (col. 11 lines 27-34). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made provide a coaxial catheter, a recycling chiller and to insulate the supply lumen of Ginsburg as taught by Saab to provide a means of differential heating, to reduce the amount of fluid used by recycling fluid and to prevent thermal treatment of tissue not intended for treatment.

Arless et al. disclose a similar apparatus that includes a metallic heat transfer element and a helical heat transfer element that enhances the surface area and the heat transfer rate of the device. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a metallic heat transfer element or a helical heat transfer element on the Ginsburg device, particularly

in view of the teaching of Arless et al. that the metallic structure and the helical structure will enhance heat transfer capabilities.

Response to Arguments

Applicant's arguments filed 4/7/03 have been fully considered but they are not persuasive. Applicant argues that Ginsburg fails to teach a circulating unit. Ginsburg is not relied upon as teaching a circulating unit, Saab has been incorporated into the rejection for teaching the use of a circulating unit.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

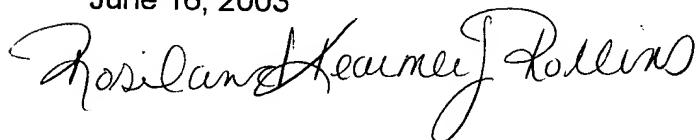
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S Kearney whose telephone number is 703/3082711. The examiner can normally be reached on Mon.-Fri. 9:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 703/3080994. The fax phone numbers for the organization where this application or proceeding is assigned are 703/3080758 for regular communications and 703/3080758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/3080858.

RK-

June 16, 2003



**ROSILAND S. KEARNEY
PRIMARY EXAMINER**